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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/630,154 | 07/29/2003 | Paula M. McCready | IL-11031 | 4005 |

7590 05/01/2006

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EXAMINER

NAVARRO, ALBERT MARK

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| ART UNIT | PAPER NUMBER |
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1645

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,154

Applicant(s)

MCCREADY ET AL.

Examiner

Mark Navarro

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 9, 12 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 8, 10, 11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 7-16 and ten sequences (SEQ ID NO: 4, 8, 12, 16, 20, 24, 28 and 32) in the reply filed on March 31, 2006 is acknowledged. The traversal is on the ground(s) that Applicant believes that the pending claims should be examined as described in MPEP 803.04, Example B, in which a claim that reads "a combination of DNA fragments comprising SEQ ID NO: 1-1000, will generally not be subject to restriction. This is not found persuasive because Applicants are not claiming a combination of DNA fragments. Rather the claims are directed to methods of detection. While the methods do result in detecting the same amplicon, i.e., SEQ ID NO: 4 or SEQ ID NO: 8, the search must be carried out on the amplicons as well as individually on the primers used to generate the amplicon. Identification of the same primers would be pertinent prior art even in the absence of disclosure of the identified amplicon, given that they would inherently amplify the same region. Accordingly, this application is restricted in view of MPEP 803.04 in that "up to 10 sequences" will be examined in a given application.

Accordingly, claims 1-3, and 7-20 are pending in the instant application, of which claims 1-3 and 17-20 have been withdrawn from further consideration as being drawn to a non-elected invention. Furthermore, claims 9 and 12 have been withdrawn from further consideration as containing greater than 10 distinct nucleotide sequences in a single application.

The requirement is still deemed proper and is therefore made FINAL.

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

2. Claims 7-8, 10-11 and 13-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 7-8, 10-11, and 13-16 recite a method for detection of *Francisella tularensis* in a sample comprising using an assay to detect a first Amplicon comprising SEQ ID NO: 4 and a second Amplicon comprising SEQ ID NO:8.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "using an assay to detect an amplicon comprising SEQ ID NO: 4 or 8" alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative

number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants claims fail to disclose how amplicons comprising SEQ ID NO: 4 or SEQ ID NO: 8 are generated. Detecting such sequences within a sample is routine in the art, however generating such amplicons in the first place requires knowledge of the specific primers and probes used to amplify the particular sequences. Without disclosure of the particular primers and probes to generate the amplicon, Applicants written description requirement is not deemed to be fulfilled. Furthermore, Applicants have disclosed the precise amplicon represented by SEQ ID NO: 4, SEQ ID NO: 8, SEQ ID NO: 12, SEQ ID NO: 16, SEQ ID NO: 20, SEQ ID NO: 24, SEQ ID NO: 28 and SEQ ID NO: 32, in other words "consisting of" the identified amplicon. Applicants disclosure fails to identify the upstream or downstream regions of this fragment, which will have a profound impact on the activity of the molecule. Accordingly, the written description of the amplicon is sufficient only for the identified fragment, i.e., "consisting of." It is noted that Applicants withdrawn claims do set forth of the specific primers and probes used to generate the Amplicon of SEQ ID NO: 4 and 8. However, the written description requirement for these probes is also only satisfied for the described probe, i.e., consisting of. Additional nucleotides on either side of the identified probe will

dramatically alter its binding interaction with other DNA molecules.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
April 27, 2006